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09/693,558	10/20/2000	Elfi Biedermann	25846-0003	7777

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HELLER EHRMAN WHITE & MCAULIFFE LLP  
275 MIDDLEFIELD ROAD  
MENLO PARK, CA 94025-3506

EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/693,558</b>	Applicant(s) <b>Biedermann et al.</b>
Examiner <b>Phyllis Spivack</b>	Art Unit <b>1614</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Apr 1, 2002

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 32-49 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 32-49 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3

6)  Other:

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A Preliminary Amendment filed June 13, 2001, Paper No. 3, is acknowledged. An Abstract is noted. Claims 1-31 are canceled. New claims 32-44 are presented. A second Preliminary Amendment filed January 8, 2002, Paper No. 5, is further acknowledged in which claims 32, 33 and 41 are amended and new claims 45-49 are presented. Accordingly, claims 32-49 represent all of the claims under consideration.

In response to a request for an election of species, Applicants have elected in Paper No. 7, filed April, 2002, the species nicotinamide as the compound having PP activity and the compound of formula I is N-[4-(1-benzoylpiperidin-4-yl)-butyl]-3-(pyridin-3-yl)-acrylamide with traverse.

The traversal is on the ground that the compounds having vitamin PP activity share a common utility and share a substantial common feature disclosed as being essential to that activity. Further, Applicants assert the compounds of formula I share a common activity as cancerostatic or immunosuppressive agents and share a common feature disclosed as being essential to that activity. Formula I is cited apparently as support for a common feature.

Applicants' arguments have been given careful consideration and are found persuasive with respect to compounds having vitamin PP that are 3-pyridylmethanols, 3-pyridylcarboxylates and 3-pyridylcarboxamides. However, The various compounds of instant formula I where the E or G terms may be heterocyclic moieties are repugnant to accepted principles of scientific classification. A plethora of compounds are encompassed within the definitions of E and G. The search required for a method and/or composition where G is dihydrobenzothienothiepinyl, for example, would vary from a method and/or composition where G is tetrahydroisoquinolinyl.

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Distinctness of the methods/compositions is evidenced by the different classification based on the many heterocycles disclosed in the specification for E and G. Based on the selection of groups for E and G, compounds of instant formula I no longer share a substantial common structural feature that is essential to activity. As to the burden of the search, classification is merely one indication of the burdensome nature of the required search. The literature search of the large number of possible compounds of instant formula I claimed herein is not necessarily co-extensive and is a major factor in determining search burden. The request for an election of species is still deemed proper.

Claims 32-49 wherein the compounds having vitamin PP activity and/or a compound of instant formula I where neither E nor G is a heterocycle, reflect the subject matter presently under consideration. The subject matter of claims 32-49 wherein E or G of formula I is a heterocycle is withdrawn from consideration by the Examiner as being drawn to non-elected inventions, 37 CFR 1.142(b).

An Information Disclosure Statement filed June 13, 2001, Paper No. 3, is further acknowledged and has been reviewed to the extent each reference is provided.

Claims 36 and 48 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants are required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Claims 36 and 48 do not further limit the subject matter from which they depend in that tryptophan is not a nicotinic acid derivative.

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Claims 32-49 are rejected under judicially created doctrine as being drawn to an improper Markush group. A proper Markush group must share a substantial structural feature disclosed as being essential. Lack of unity of invention has been found to exist since a common nucleus among the various compounds having vitamin PP activity and among the compounds of formula I having a plethora of possible heterocyclic groups is absent. A prior art reference anticipating the claims under 35 U.S.C. 102 with respect to one species would not render the same claims obvious under 35 U.S. C. 103 with respect to another species. The members of the Markush groups possess widely different properties and are not considered functionally equivalent.

Deletion of the non-elected subject matter would resolve the issue.

The claims are examined fully with respect to the elected species only and further to the extent necessary to determine patentability. See MPEP 803.02.

Claims 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The recitation within the definitions of R<sup>1(I)</sup> through R<sup>4(I)</sup>, A<sup>(I)</sup> and D<sup>(I)</sup> "functional group" renders the claims indefinite. The metes and bounds of the term cannot be precisely determined. Those groups contemplated should be recited.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 32-36 are rejected under 35 U.S.C. 102(a) as being anticipated by Budihardjo et al., Clinical Cancer Research.

Budihardjo teaches the therapeutic administration of the nicotinamide derivative, 6-aminonicotinamide, which can be metabolized in vivo to a compound with vitamin PP activity, as a modulator of the action of various antineoplastic treatments.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Artemov, V.A., Vopr. Eksp. Klin. Immunol. (abstract).

Artemov teaches the administration of 5-hydroxy-6-methyl-3,4-pyridinemethanol, a compound of instant formula II, pyridoxine, to reduce the immunodepressive side effect of the cancerostatic agent 6-mercaptopurine.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

July 1, 2002

*Phyllis Spivack*

**PHYLLIS SPIVACK**  
**PRIMARY EXAMINER**